REMARKS

The Official Action dated November 13, 2006 has been carefully reviewed. In view of the amendments submitted herewith, and the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

As a preliminary matter, Applicants submit herewith a copy of the priority GB application in accordance with the Examiner's requirement. Applicants have also cancelled claims 18-40 and 42 which have been withdrawn from consideration in response the initial restriction requirement. This cancellation is without prejudice and Applicants reserve the right to file one or more continuation applications on the subject matter of the cancelled claims.

At page 3 of the Official Action, the Examiner has rejected claims 2, 5, 9, 11-14, and 41 under 35 U.S.C. §112, first paragraph as allegedly lacking enablement for variants of SEQ ID NOS: 1, 2 and 4.

The Examiner has also rejected claims 2, 5, and 11-13 under 35 U.S.C. §112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention.

The foregoing rejections constitute all of the grounds set forth in the November 13, 2006 Official Action for refusing the present application. Each of these objections and rejections are traversed for the reasons set forth below.

THE CLAIMS AS AMENDED SATISFY THE ENABLEMENT REQUIREMENTS OF 35 U.S.C. §112, FIRST PARAGRAPH

The Examiner has maintained the rejection of claims 2, 5, 9, 11-14, and 41 contending that the specification fails to enable the polypeptide variants of SEQ ID NO: 2. Applicants respectfully disagree.

At the outset, Applicants have amended claim 2 in keeping with the Examiner's helpful suggestion, thereby removing any perceived undue breadth from the claim. Claim 2 as amended, is now directed to an isolated polypeptide variant having lipase/acyltransferase activity wherein the variant polypeptide comprises amino acids 190-390 of SEQ ID NO: 2 or wherein the variant polypeptide comprises a sequence which is 96% identical to amino acids 190-390 of SEQ ID NO: 2, said polypeptide optionally comprising an additional polypeptide sequence and optionally being glycosylated.

Applicants submit that this claim is fully enabled by the disclosure in the specification. First, Applicants exemplify SEQ ID NO:2 which comprises an additional peptide sequence. This is SEQ ID NO: 4 which is SEQ ID NO:2 plus an amino acid sequence comprising a HIS tag. Second, Applicants take exception to the Examiner's apparent requirement that Applicants indicate which amino acid residues are glycosylated. The skilled person is well aware that glycosylation signals are conserved in nature and for N-linked glycosylation the consensus sequence is Asn-X-Ser/Thr. While O-linked glycoslyation is a bit more random, many kits are commercially available to determine the glycosylation state and sites in a protein. See the Sigma Aldrich catalog, Glycoprotein Detection Kit, Product Code GLYCO-PRO. Thus, Applicants submit that each feature of claim 2 is enabled.

Claims 9 and 14 have been cancelled, thereby rendering the rejection of these claims moot.

Claims 11-13 have been amended to recite particular variant types (e.g., insertion, deletion or derivative mutants of the polypeptide encompassed by claim 2 and have been further amended to recite that such variants are recognized by antibodies which are immunospecific for SEQ ID NO: 2.

Regarding the Examiner's assertion that Applicants have not which are immunospecific for SEQ ID NO: 2, thereby eliminating the language found objectionable by the Examiner.

The definiteness of claim language may not be analyzed in the abstract, but must be considered in light of the teachings of the prior art and of the particular application disclosure. In response to the Examiner's apparent requirement of a recitation of amino acids to be glycosylated in claim 2, Applicants reiterate that determination of glycosylation sites is well within the purview of the skilled artisan. Clearly, the skilled person appreciates that the polypeptide of SEQ ID NO: 2 may or may not be glycosylated and Applicants are entitled to claims to polypeptides comprising this post-translation modification. Inasmuch as the skilled person would readily comprehend the subject matter encompassed by claim 2 as amended, Applicants submit that the rejection of the claims on this basis is untenable and should be withdrawn.

CONCLUSION

It is respectfully requested that the amendments presented herewith be entered in this application, since the amendments are primarily formal, rather than substantive in nature. This amendment is believed to clearly place the pending claims in condition for allowance. In any event, the claims as presently amended are believed to eliminate certain issues and better define other issues which would be raised on appeal, should an appeal be necessary in this case.

The present communication is completely responsive to the issues raised in the Official Action of November 13, 2006. Applicants believe that the claims as they stand are in condition for ready allowance. In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, established regions of the protein structure which can be modified without affecting lipase/acyltransferase activity, Applicants submit that the level of skill in this are area is high and the skilled person could readily generate and assess mutations falling within the identity requirements of the claims which retain lipase acyltransferase function. Indeed, the present inventors have generated many different variants which fall within the scope of the present claims which retain enzymatic activity. Finally, the Examiner's attention is respectfully drawn to a recent Federal Circuit decision Falkner v. Inglis, involving a production of an improved vaccine by deleting or inactivating essential viral genes, where the Court held that "there is no *per se* rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure." Falkner v. Inglis, 448 F.3d 1357, 1366 (Fed. Cir. 2006). Moreover, the Court reiterated that the mere fact that the experimentation (in creating the inactivated mutants) may be difficult and time consuming does not mandate a conclusion that such experimentation would have been considered undue in the art. Thus, the lower court's holding that the claims were enabled was upheld.

In light of the amendments to claims 2, 11-13 and the cancellation of claims 9 and 14, Applicants submit that specification is fully enabling for the present claims. Accordingly, Applicants request that the rejection of the foregoing claims for inadequate enablement be withdrawn.

THE METES AND BOUNDS OF CLAIMS 2, 5 AND 11-13 ARE CLEAR TO ONE OF ORDINARY SKILL IN THE ART

Claims 2, 5 and 11-13 have been amended to recite antibodies the Examiner is requested to telephone the undersigned attorney at the phone number given below.

Respectfully submitted,
DANN, DORFMAN, HERRELL AND SKILLMAN
A Professional Corporation

By Kathleen D. Rigaut
Kathleen D. Rigaut, Ph.D., J.D.
Registration No. 43,047

Telephone: (215) 563-4100
Facsimile: (215) 563-4044

Enclosures: Copy of GB priority application